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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,204	06/22/2001	Moshe Fleshner-Barak	1662/53002	7559

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KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,204	FLESHNER-BARAK ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *90-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *90-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt request for extension of time, amendment and remarks filed 9/26/06. Claims 90 and 93 are amended. Claims 90-96 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 90-96 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is New Matter rejection.

The recitation of the ranges

From about 13 wt-% to about 30 wt-% superdisintegrant is not supported by the as filed specification,

About 6 wt-% to about 12 wt-% tannic acid is not supported by the as filed specification,

About 60 to about 85 wt-% of a hydrogel is not supported by the as filed specification.

Applicant points to the specification at page 13, lines 27-28 for support. However, page 13, lines 27 and 28 supports a) 20 wt. % to about 70 wt. % hydrogel, b) from about 10 wt. % to

about 75 wt. % superdisintegrant, the superdisintegrant can also range from about 30 wt. % to about 55 wt. % superdisintegrant and c) from about 2 wt. % to about 12 wt. % tannic acid, which can be present at preferred percent of about 5 wt. % (.+-.2 wt. %). Therefore, the ranges now recited in the amended claims are not supported by the original claims.

The above rejection may be overcome by removing the new matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 90-96 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Burnside et al. (US 6,322,819) in view of Swanson et al. (US 4,326,525).

Burnside discloses multiple pulsed dose drug delivery system (abstract) comprising a core (column 6, lines 52-56) that includes one or more amphetamine salts coated with immediate release coating and one or more amphetamine salts that are covered with enteric coating (column 3, lines 25-48; column 4), and additives, the additives are binders, disintegration agent, filling agent, surfactant, solubilizers and stabilizers (column 6, line 64; column 7, lines 1, 6, 11, 14 and 18). Hydroxypropyl methylcellulose is an example of a binder additive (column 6, lines 63-67); cross-linked carboxymethylcellulose (AC-DISOL), sodium starch glycolate (EXPLOTAB), crosslinked polyvinylpyrrolidone (PLASDONE XL) are examples of disintegration agents

(column 7, lines 1-5); mannitol, lactose, polyethylene glycol are few of the fillers in Burnside (column 7, lines 6-10); PLURONIC is a surfactant in Burnside (column 7, lines 10-13); methylphenidate is specifically disclosed as an amphetamine derivative (column 7, lines 48-55).

The cross-linked carboxymethylcellulose (AC-DISOL), sodium starch glycolate (EXPLOTAB), crosslinked polyvinylpyrrolidone (PLASDONE XL) meet the limitation of the claimed disintegration agents.

Burnside discloses a composition comprising disintegration agent and methylphenidate and the composition is multi-particulate with some cores coated with enteric coating material and others coated with immediate release coating materials. The formulation of Burnside does not contain tannic acid or tannin or gallototannic acid.

However, Swanson discloses a dosage form containing methylphenidate (column 7, line 16), tannic acid (column 7, line 44; column 8, line 16). Thus, Swanson is relied upon for disclosing methylphenidate formulation that comprises tannic acid. The amended claims now recite ranges in amounts of superdisintegrants, hydrogel and tannic acid. However, there is no demonstration that the recited amounts provides unexpected results to the claimed dosage form. Specifically, Burnside is silent in the amounts of these ingredients, which implies that any amount in any combination would provide formulation for the effective release of methylphenidate. Furthermore, the claimed broad ranges suggests varied combinations in varied amounts. In the absence of factual evidence, the recited amounts of the hydrogel composition, the tannic acid and the superdisintegrants would not distinguish the claimed invention over the prior art.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the methylphenidate multi-core dosage form according to Burnside. One having ordinary skill in the art would have been motivated to include tannic acid in the formulation of Burnside with the expectation of producing and providing multiple pulsed dose of amphetamine salts and specifically methylphenidate.

Response to Arguments

5. Applicant's arguments filed 9/26/06 have been fully considered but they are not persuasive.

Applicant argues that the combination of Burnside and Swanson does not disclose all the elements of the claims and that there is no motivation to combine the two references. That Burnside relies on "laundry list of numerous materials of a variety of genres that can be used to make the pellets"/cores, which are coated with either or both of a protective layer and an enteric coating in any order. The present invention does not have a compartment as in the osmotic device of Swanson. That the superdisintegrant of the claimed invention must be part of the matrix in the instant invention and not isolated in a coated core as in Burnside. That Burnside has the drug in a solid core and Swanson has the beneficial agent enclosed in a compartment for dispensing under osmotic pressure. That Burnside or Swanson alone or in combination would have enabled the skilled artisan of today to make the inventive composition.

Response:

The combination of Burnside and Swanson discloses the claimed composition because a)

Burnside discloses the claimed composition as described in the rejection except that Burnside does not include tannic acid in the composition. Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Swanson provides a composition where methylphenidate and tannic acid are combined to aid in formation of acid addition salt of the methylphenidate that upon release would release the methylphenidate without undesired toxicological effects. Thus, Swanson is relied upon a disclosure that tannin/tannic acid can be combined in a composition. Therefore, there exists suggestion to combine tannin/tannic acid with mthylphenidate in order the salt formed between the basic drug and the tannic acid would be release without undesired toxicological effect.

Regarding laundry lists, it is noted that as it regards to amphetamines, which is the active agent of Burnside, methylphenidate is the first on the list of the amphetamines (col. 5, lines 12, 21, 32, 33; column 7, lines 44-54) and applicant does not point to where else in Burnside the laundry list is disclosed. However, the list of hydrogel materials is limited to the celluloses. The claims do not exclude the compartment of Swanson and Swanson is not relied upon for teaching either compartment or osmotic dosage form. A matrix refers to any material that surrounds and encompasses pharmaceuticals in the case of pharmaceutical delivery. Thus, in broad sense, Burnside contains the active agent and the carriers in a matrix. Therefore, combining the suggestion of Swanson to incorporate tannin/tannic acid with methylphenidate,

leads to the formulation where the Burnside formulation contains tannic acid. The combination of the suggestion of Swanson in combination with the teachings of Burnside discloses all the claimed limitation.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER